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October 20, 2004

Dr. Lester M. Crawford, Acting Director
Food and Drug Administration
5600 Fishers Lane, Room 1471
Mail Stop HF-1
Rockville, MD 20857

Dear Dr. Crawford:

Please consider setting aside the Initial Decision by the Administrative Law Judge recommending the withdrawal of the NADA for Baytril (enrofloxacin), or appointing a select panel including practicing poultry veterinarians or other experts qualified in poultry practice, such as diplomates of the American College of Poultry Veterinarians, or active members of the American Association of Avian Pathologists, to review this matter and make a recommendation.

I am the senior production veterinarian for Goldsboro Milling Company. In that capacity, I administer health programs for over 9 million market turkeys and 250,000 turkey breeders annually and have done so for over 18 years, with dotted line responsibilities into our 70,000 sow and 1200 head brood cow divisions. I am a second-generation turkey producer; my academic credentials include a DVM (ISU '74), a MS (University of Minnesota '76, major – avian microbiology, minor – biometry) and a PhD (NCSU '91, major - veterinary pathology, minor-poultry science). I am certified in poultry production and management by the American Registry of Professional Animal Scientists and am a diplomate of the American College of Poultry Veterinarians with a term on the Board of Governors. I have served as the National Turkey Federation (NTF) liaison to the AVMA Steering Committee on Antibiotic Resistance, and helped prepare the Judicious Use Guidelines for Poultry. I am an adjunct associate professor with the Population Health & Pathobiology Department at North Carolina State University, and serve NTF on the Live Production Committee. I hold memberships and usually committee assignments with the American Veterinary Medical Association, the American Association of Avian Pathologists, the Poultry Science Association, the US Animal Health Association, the American Association of Food Hygiene Veterinarians, the Association of Veterinarians in Turkey Production, and the American Association of Swine Veterinarians. I am licensed to practice veterinary medicine in North Carolina.

I have followed CDC and PHS opinion-making on fluoroquinolone use in poultry for years, and contacted Bayer and AHI to volunteer as an expert witness on their behalf as soon as it became apparent that input from clinical poultry practice was needed.

GOLDSBORO MILLING COMPANY
FEED PRODUCTION UNIT

SLEEPY CREEK FARMS
TURKEY HATCHERY

SLEEPY CREEK TURKEYS
TURKEY PRODUCTION UNIT

BEAR CREEK FARMS
BREEDER PRODUCTION UNIT

GOLDSBORO MILLING GRAIN
GRAIN BUYING UNIT

MAXWELL FARMS
FARM MANAGEMENT

COLD CREEK FARMS
TURKEY PRODUCTION UNIT

GOLDSBORO HOG FARMS
SWINE PRODUCTION UNIT

G & L PROCESSING
FARM MANAGEMENT

CAROLINA TURKEYS
TURKEY PROCESSING PLANT

CAROLINA TURKEYS OF VIRGINIA
TURKEY PROCESSING PLANT

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I will not reiterate my testimony or comments to the Docket , or my original comments on the NOOH although you may find them informative –a search of the FDA website under my name will produce them – if not, I will be happy to furnish copies.

My original testimony submitted to the ALJ prior to the motions to strike might also be informative. Of course, I believe my testimony should have remained intact, in part because an entire section was removed because I did not explain why I chose the dates I did for the data presented. I didn't understand this would be an issue – the dates chosen were 5 years of data ending just prior to the NOOH. Another section was removed due to a perceived grammatical error – I used the words “may be” instead of “have been and will in the future be”. The ALJ apparently believed I was posing a hypothetical situation rather than one that had actually occurred and would continue to occur. In several other instances, the ALJ seemed to have difficulty distinguishing between my professional opinion, my personal knowledge, referenced facts, and areas where I have personal expert experience. Consequently I believe substantial portions of my testimony were stricken in error if I understand the intent of OR31. Indeed, I am not sure the ALJ understood in what areas a senior poultry clinician with my training is expert.

I was particularly startled by the ALJ's assertion that “Nevertheless, there are in fact effective alternatives to enrofloxacin including chlortetracycline, oxytetracycline, sulfomycin, and tetracycline”. The ALJ completely set aside the opinion of every single poultry clinician testifying - that there are no current therapeutic replacements for enrofloxacin. Setting aside that clinical experience, which is vastly greater than that of the ALJ or CVM staff, seems peculiar at best. On pharmacological grounds alone I find the assertion that a bacteriostatic antibiotic is a functional replacement for a bacteriocidal antibiotic in the face of a gram-negative bacteremia associated with either colibacillosis or fowl cholera to be extraordinarily uninformed. I have also been completely unable to find any form of sulfomycin suitable for use in poultry and would appreciate any guidance you could provide on its availability for drinking water use. I am unable to locate a source.

I am convinced the exhibits and testimony in this matter have not been impartially reviewed by knowledgeable authority. I urge you to consider either setting this opinion aside, or convening a panel of informed, impartial experts to render a recommendation that considers all the information available. The well-being of my patients is an issue that I believe should be treated with some degree of gravitas by knowledgeable authority.

Sincerely,

A handwritten signature in black ink, appearing to read "Eric Gonder", written over a horizontal line.

Eric Gonder, DVM, MS, PhD, PAS, ACPV

cc: Food and Drug Administration, Dockets Management Branch
Dr. Lyle Vogel, NTF